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Reregistration Eligibility Decision for Para-dichlorobenzene

US EPA ARCHIVE DOCUMENT

Reregistration Eligibility Decision (RED) for
Para-dichlorobenzene

List C

Case No. 3058

Approved by: _____

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Special Review and Reregistration Division

Date: September 28, 2007

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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
DCI	Data Call-In
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EPA	Environmental Protection Agency
EUP	End-Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLN	Guideline Number
HED	Health Effects Division
HDT	Highest Dose Tested
IRIS	Integrated Risk Information System
LADD	Lifetime Average Daily Dose
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LIP	Label Improvement Program
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOA	Mode of Action
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NCEA	National Center for Environmental Assessment
NDETF	Non-Dietary Exposure Task Force
NLAA	Not Likely to Adversely Affect
NR	Not Required
NOAEL	No Observed Adverse Effect Level
NOAEL _{HEC}	No Observed Adverse Effect Level Human Equivalent Dose.
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PII	Primary Irritation Index
PK	Pharmacokinetic
ppb	Parts Per Billion
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfC	Reference Concentration
RfD	Reference Dose
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TEAM	Total Exposure Assessment Methodology
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
UF _{db}	Database Uncertainty Factor

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Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and ecological risk reregistration memorandum for the para-dichlorobenzene and is issuing its risk management decision. The human health risk assessment and ecological risk reregistration memorandum, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products. As a result of this review, EPA has determined that para-dichlorobenzene-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

Para-dichlorobenzene is a fumigant insecticide. The majority of its pesticidal use is as a moth repellent to protect garments from insect damage and in and around birdcages for the control of lice and ticks. There are no outdoor uses registered for para-dichlorobenzene; therefore, ecological risk was not assessed. Since para-dichlorobenzene does not have any food or other outdoor uses, the only uses assessed are indoor residential uses and a single occupational use. Of the risk scenarios assessed, only the risk from episodic ingestion of mothballs by toddlers was of concern. Mitigation measures, possibly including but not limited to, special packaging and precautionary label language, will be required to address this potential risk of concern.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). Reregistration involves a thorough review of the scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the “no unreasonable adverse effects” criterion of FIFRA.

This document summarizes EPA’s human health risk assessment, ecological reregistration memorandum, and reregistration eligibility decision (RED) for para-dichlorobenzene. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health risk assessment and ecological reregistration memorandum; Section IV presents the Agency’s decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for para-dichlorobenzene and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (<http://www.regulations.gov>) under docket number EPA-HQ-OPP-2007-0937.

II. Chemical Overview

A. Regulatory History

The Agency's predecessor for pesticide registrations, the U.S. Department of Agriculture (USDA), first registered a product containing para-dichlorobenzene in 1947. The Agency has never issued a Registration Standard for this product. However, in the early 1990s, the Agency required the technical registrant to supply acute toxicity data on the technical product. In the latter half of the 1990s, the Agency initiated a Label Improvement Program (LIP) to update the precautionary text, use directions, storage, and disposal instructions to reduce exposure to para-dichlorobenzene and other chemicals, especially when used in homes.

Currently, the Agency has 28 products registered; of those, 5 are manufacturing-use products and 23 are end-use products. All are registered under Section 3 of the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA). There are no Special Local Needs (SLNs) registrations. Most products (18) are for moth and carpet beetle control inside of airtight spaces (closets, chests, and garment bags) in homes. Some products (3) are also used indoors to kill lice and mites on birds in cages. One product is used to kill wax moths in empty beehives and bee houses stored indoors. Also, one product is used to repel Norway rats and house mice from indoor storage areas and to repel gray squirrels from attics.

B. Chemical Identification

PARA-DICHLOROBENZENE:



Para-dichlorobenzene is a colorless or white crystalline solid with a strong, pungent odor.

Common Name:	Para-dichlorobenzene
Chemical Name:	1,4-dichlorobenzene
Other Names:	PDCB, P-Dichlorobenzene
Chemical Class:	Fumigant Insecticide
PC Code:	061501
Case Number:	3058
CAS Registry Number:	106-46-7
Molecular Weight:	147
Empirical Formula:	C ₆ H ₄ Cl ₂
Technical Registrants:	PPG Industries, Inc. and Solutia, Inc.

C. Use Profile

The following information on the currently registered uses includes an overview of use sites and application methods. A detailed table of the uses of para-dichlorobenzene eligible for reregistration is contained in Appendix A.

Type of Pesticide: Fumigant Insecticide.

Target Organism: The primary target pests are moths, carpet beetles, lice, and mites.

Use Sites: Para-Dichlorobenzene is limited to indoor use only. It is used as a moth and beetle repellent in products which are applied to commercial and residential use sites such as closets and storage containers, and to repel lice and mites from bird cages. It is also used in empty bee supers (stored indoors), to repel wax moths. When formulated into varpal rope, it is used in attics to repel snakes, mice, rats, squirrels, and attic wombats.

Use Classification: Para-dichlorobenzene products are designated as general use.

Formulation Types: Cakes, crystals, balls, sachetes, impregnated strips, blocks, varpal rope, and flakes.

Application Methods: By hand.

Application Rates: It is applied as a moth repellent in moth balls, flakes, crystals, cakes, and sachetes at rates ranging from 0.01 pounds of active ingredient per cubic foot (lbs ai/ft³) to 0.02 lbs ai/ft³. When formulated into a block, it is applied at a maximum application rate of 0.025 lbs ai/ft³. When formulated into Varpel rope, it is applied at a rate of 50 feet of product per 5,000 ft³. It is applied to beehives at a maximum application rate of 0.19 lbs ai/hive. When applied in bird cages, the maximum application rate is 0.017 lbs ai/cage.

Application Timing: The application timing is generally not mentioned on existing para-dichlorobenzene labels, although some labels recommend re-application after six months, while others recommend use as needed.

D. Estimated Usage of Pesticide

Approximately 5 million lbs of para-dichlorobenzene are marketed on average per year. The majority of the usage is in moth repellent products. However, detailed usage information is not available.

III. Summary of Para-dichlorobenzene Risk Assessments

The following is a summary of EPA's revised human health risk assessment for para-dichlorobenzene, as presented fully in the document, *Para-dichlorobenzene: HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated September 28, 2007. Since there are no outdoor uses of para-dichlorobenzene, an ecological risk assessment was not required, as is described in the *Para-dichlorobenzene: EFED Memorandum in Support of the Reregistration Eligibility Decision*, dated September 28, 2007. These documents are available in the OPP Public Docket, docket number EPA-HQ-OPP-2007-0937, and may also be accessed through the Agency's website at <https://www.regulations.gov>. Hard copies of these documents may be found in the OPP public docket under this same docket number. The purpose of the following summary is to assist the reader by identifying the key features and findings of the paradichlorbenzene human health risk assessment and to help the reader better understand the conclusions reached in the assessment.

EPA's use of human studies in the para-dichlorobenzene risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure, hazard, and risks from all sources, which for para-dichlorobenzene are indoor residential uses and a single occupational use. There are no registered food uses for para-dichlorobenzene, and since there are no outdoor uses, drinking water exposure is not anticipated. A dietary risk assessment was not conducted due to the absence of potential drinking water and food exposure. The Agency's human health assessment considers all U.S. populations, including infants and young children. For more information on the para-dichlorobenzene human health risk assessment, see *Para-dichlorobenzene: HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated September 27, 2007.

1. Toxicity of Para-dichlorobenzene

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects, such as skin or eye damage, and lifetime or chronic effects, such as cancer, developmental effects, or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for para-dichlorobenzene and has determined that the toxicological database is reliable and sufficient for reregistration.

a. Acute Toxicity Profile

Para-dichlorobenzene is considered moderately toxic on an acute basis by the oral and dermal routes (Toxicity Category III). It is considered to be of low toxicity by the inhalation route (Toxicity Category IV). It is categorized also as moderately toxic for primary eye irritation (Toxicity Category II) and dermal irritation (Toxicity Category III). Para-dichlorobenzene did not induce delayed contact sensitivity (dermal sensitization) when tested in guinea pigs. The acute toxicity profile for para-dichlorobenzene is summarized in Table 1 below.

Guideline	Study Type	MRID	Results	Toxicity Category^a
870.1100	Acute Oral	40521001	LD ₅₀ = 3863 mg/kg (males) LD ₅₀ = 3790 mg/kg (females)	III
870.1200	Acute Dermal	40521001	LD ₅₀ >6000 mg/kg	III
870.1300	Acute Inhalation	41410901	LC ₅₀ = > 6.00 mg/L, highest attainable concentration	IV
870.2400	Primary Eye Irritation	42205301	Conjunctivitis and corneal opacity cleared in 10 days, iritis cleared in 72 hours, vascularization of the cornea cleared in 10 or 13 days. The maximum total irritation scores ranged from 20 to 47 indicating a mild irritant.	II
870.2500	Primary Dermal Irritation	42205302	Moderate to severe erythema persisted for 48-72 hours in most animals. Primary irritation index (PII) = 2.9	III
870.2600	Skin Sensitization	42205303	Negative under the condition of the test.	N/A

a. These technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

b. Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for para-dichlorobenzene are listed in Table 2 below. The toxicity of para-dichlorobenzene has been investigated in several animal species by the oral and inhalation routes under chronic and subchronic exposure conditions. Oral studies in rodents and non-rodent species indicate that the liver and kidney are common and primary target organs/tissues. Decreased body weight, reduced organ weights, and changes in hematological parameters are considered some of the common effects for this chemical. The volatility of this material makes the inhalation route the most likely route of human exposure under the current use profile as a moth repellent. Oral exposure is unlikely under the current use profile, and may be limited to episodic ingestion by children. Inhalation exposure was assessed for the following exposure durations: short-term (1-30 days), intermediate-term (1-6 months), or chronic (>6 months). Dermal exposures are expected to be short-term in nature; therefore, intermediate-term and chronic dermal endpoints were not selected. Inhalation (short-term, intermediate-term and chronic), short-term dermal, and incidental oral (*i.e.*, episodic ingestion) exposures have been assessed.

The available database is considered adequate to characterize any potential for prenatal or postnatal risks for infants and children based on the current use profile for para-dichlorobenzene. The data available on para-dichlorobenzene included two acceptable prenatal inhalation developmental toxicity studies in rats and rabbits and a two-generation inhalation reproduction study in rats. The data provided no indication of increased sensitivity of either fetal animals to (*in utero*) exposure to para-dichlorobenzene or offspring exposed post-natally to para-

dichlorobenzene. Furthermore, the No Observed Adverse Effect Level (NOAEL) of 20 ppm generated in the chronic inhalation toxicity/carcinogenicity study and the NOAEL of 55 ppm generated in the 13-week inhalation toxicity study in rats provided the most sensitive endpoints for all exposure duration scenarios. The regulatory endpoints defined below exceed effect levels seen in the developmental and reproductive toxicity studies in rats and rabbits and, therefore, will be protective of all population subgroups, including infants and children.

To estimate residential (dermal, incidental oral, and inhalation) and occupational (dermal and inhalation) non-cancer risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. For para-dichlorobenzene, the target MOE (i.e., level of concern) for incidental oral and dermal exposures is 100. This includes the standard uncertainty factors (UF) of 10X for intraspecies extrapolation and 10X for interspecies variation. For inhalation exposure, a UF of 30 was used to account for both intraspecies extrapolation (10X) and interspecies variations (3X), although traditionally, the uncertainty factor for interspecies extrapolation is 10X. The 10X is often considered to be made up of two components, each equal to a half-log value: 3.16 for pharmacokinetics, which describes how a chemical gets to the target tissue, and 3.16 for pharmacodynamics, which describes how the target tissue responds to the chemical. A full interspecies factor of 10X was not used in this case because the reference concentration (RfC) methodology developed by the Agency was followed in which dosimetry adjustments were used to derive a No Observed Adverse Effect Level Human Equivalent Dose (NOAEL_{HEC}), which accounts for the pharmacokinetic component of the interspecies extrapolation, thus allowing a reduction of the interspecies factor from 10X to 3X.

Exposure Scenario	Dose Used in Risk Assessment	Level of Concern (LOC) for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term (1-30 days)	NOAEL= 25 mg/kg/day	UF _A = 10x UF _H = 10x Total UF= 100X	<u>4-Week oral toxicity study-dog</u> NOAEL= 25 mg/kg/day LOAEL= 75 mg/kg/day, based on increased liver weight in males and increased alkaline phosphatase and liver weight, irritation to GI tract in females.
Dermal Short-Term (1-30 days)	NOAEL ≥ 300 mg/kg/day	UF _A = 10x UF _H = 10x Total UF= 100X	<u>21-day dermal-rat</u> NOAEL ≥ 300 mg/kg/day (HDT) LOAEL ≥ 300 mg/kg/day.
Inhalation Short-Term (1-30 days)	NOAEL= 150 ppm or NOAEL _{HEC} = 180.36 mg/m ³	UF _A = 3x UF _H = 10x Total UF= 30X	<u>28-Day inhalation toxicity - dog</u> Decreased body weight and food consumption, hematological and clinical chemistry changes, increased absolute and relative liver weight, liver histopathological changes, decreased absolute heart weight and absolute and relative adrenal weights seen in both sexes at the next higher dose, LOAEL, of 500 ppm.

Inhalation Intermediate-Term (1-6 months)	NOAEL= 55 ppm NOAEL _{HEC} = 58.92 mg/m ³	UF _A = 3x UF _H = 10x Total UF= 30X	13-Week Inhalation toxicity - mouse hematological changes seen at the next higher dose, LOAEL, of 120 ppm.
Inhalation- Chronic exposure (6-12 months)	NOAEL= 20 ppm NOAEL _{HEC} = 0.56 ppm or 3.4 mg/m ³	UF _A = 3x UF _H = 10x Total UF= 30X	Toxicity/carcinogenicity- rat Olfactory epithelium changes observed at the next higher dose, NOAEL, of 75 ppm
Cancer (oral, dermal, inhalation)	<p>Not Likely to be Carcinogenic to Humans below doses that do not perturb normal liver homeostasis.</p> <p>Based on the Integrated Risk Information System (IRIS) evaluation draft document of May 2006, the low dose linear extrapolation approach was suggested. "The recommended inhalation risk unit for para-dichlorobenzene is $4 \times 10^{-3}(\text{mg}/\text{m}^3)^{-1}$, based on hepatocellular tumors in male and female mice."</p>		
<p>NOAEL = no observed adverse effect level. NOAEL_{HEC} = no observed adverse effect level human equivalent dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). N/A = not applicable.</p>			

2. Carcinogenicity of Para-dichlorobenzene

In its meeting of 02/21/2007, the Health Effect Division (HED) Cancer Assessment Review Committee (CARC) determined that para-dichlorobenzene has been tested adequately by the oral and inhalation routes in two acceptable carcinogenicity studies in rats and mice. The treatment was associated with increased liver tumors in both sexes of mice dosed orally or exposed to para-dichlorobenzene via inhalation, and increased incidences of renal tumors in male, but not female, rats when the chemical was administered orally but not via inhalation. The male rat kidney tumors were judged to have been produced via the nongenotoxic-cytotoxic alpha-2u-globulin pathway, which is considered to be specific to the male rat with no counterpart for human beings and, thus, not relevant for human cancer risk assessment.

In accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2007), the CARC classified para-dichlorobenzene as "Not Likely to be Carcinogenic to Humans" based on evidence that a non-mutagenic mode of action (MOA) involving mitogenesis was established for para-dichlorobenzene induced liver tumors in mice and that the carcinogenic effects are not likely below a defined dose that does not perturb normal liver homeostasis (e.g., increased liver cell proliferation). Mitogenic chemicals act by promoting the clonal expansion of preneoplastic cells by stimulating cell proliferation. A mitogenic chemical stimulates cell proliferation in the target organ without obvious cytotoxicity or cell death. Another important feature of this MOA is that the mitogenic effect is not persistent over time; instead, it is resolved and then is manifested within proliferative foci, which are considered preneoplastic lesions. Through continuous exposure, it is these preneoplastic lesions that develop into tumors. This liver mode of action is generally associated with an increase in metabolizing enzymes. In the case of para-dichlorobenzene, there is a good dose correlation between liver tumors, hepatic microsomal enzyme induction, and cell proliferation in the absence of overt liver toxicity consistent with mitogenesis. Dose concordant morphologic characteristics, *i.e.*, liver

hypertrophy and liver weight increases, were consistent with this mitogenic mouse liver response.

3. Metabolites and Degradates

As this chemical only has indoor uses, no plant, livestock, or water metabolism studies were submitted, nor or are they required. The Agency reviewed the metabolism of para-dichlorobenzene using the only data available (rat), which show the conjugates of 2,5-dichlorophenol in urine after ingestion of para-dichlorobenzene. This does not present a concern, since the primary route of exposure is inhalation, and no metabolites were detected in an inhalation study. Furthermore, the Agency is not aware of any degradate formed at the site of application to which people might be exposed by the potential routes of exposure (ingestion, dermal contact, or inhalation).

4. Dietary Risk (Food + Water)

There are no food uses currently registered for para-dichlorobenzene; therefore, dietary exposure is not of concern. Furthermore, since there are no outdoor uses for para-dichlorobenzene, drinking water exposure is not anticipated. Due to the lack of potential food and drinking water exposure, a dietary assessment for para-dichlorobenzene was not conducted.

5. Residential Non-Cancer Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure. For para-dichlorobenzene, the Agency has evaluated potential exposure and risk to para-dichlorobenzene for homeowners who handle (apply) products containing para-dichlorobenzene. The Agency also evaluated potential post-application risk to adults and children entering para-dichlorobenzene-treated areas.

To estimate residential (inhalation, dermal, and episodic ingestion) risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the toxicity endpoint (NOAEL or NOAEL_{HEC}) selected for risk assessment to the exposure. This MOE is compared to a level of concern (LOC), which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. For para-dichlorobenzene, the uncertainty factors are 100 for both dermal and episodic ingestion exposures, and 30 for short-term, intermediate-term, and chronic inhalation exposures. A summary of para-dichlorobenzene residential risk follows. For further information on residential risk, refer to the *Para-dichlorobenzene: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED)*, dated September 28, 2007.

a. Residential Handler Non-Cancer Risks

The Agency determined that there is the potential for residential handlers to be exposed to para-dichlorobenzene during application. Of para-dichlorobenzene's registered residential uses, the application of mothballs to sites such as closets and drawers by hand were considered the exposure scenarios with the greatest potential for exposure. The Agency anticipates handler inhalation exposure during the application process; however, appropriate inhalation handler

exposure data are not available to assess this scenario, therefore, only dermal exposure was assessed for residential handlers. Exposure data does exist for short-term exposure from post-application inhalation exposure to areas treated with para-dichlorobenzene, and this exposure scenario has been assessed. The Agency assumes that the short-term post-application inhalation assessment is protective for handler inhalation exposure, since measured concentrations of para-dichlorobenzene would likely be greater due to the time allotted in the exposure study for the product to accumulate in the enclosed areas that were treated. Since handler dermal exposure durations are expected to be short-term only, intermediate-term and chronic dermal exposures were not assessed. Since there were no chemical-specific exposure data addressing the use of a hand for indoor mothball applications, the dermal unit exposure values were based on surrogate data from naphthalene, another chemical which is also used in mothballs.

The residential handler dermal MOEs for both scenarios assessed (closets and drawers) were greater than 100 (MOE = 33,000 and 224,000, respectively) and, therefore, are below the Agency's LOC.

b. Residential Post-Application Non-Cancer Risks

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Unlike residential handler exposure, for which the Agency assumed only adults will be handling and applying para-dichlorobenzene products, individuals of varying ages can potentially be exposed when reentering or performing activities in areas that have been previously treated.

Of the registered residential uses of para-dichlorobenzene, the greatest potential for post-application inhalation exposures is anticipated after moth ball applications are made to areas such as closets and dresser drawers. For para-dichlorobenzene, the adult and toddler inhalation exposure estimates are the same, since the endpoints derived from the inhalation toxicity studies (all durations) were adjusted for pharmacokinetic (PK) differences when $NOAEL_{HECS}$ were calculated. Therefore, post-application inhalation risk was assessed for adults only. There is also a potential for post-application exposure to children ingesting mothballs. The Agency does not consider ingestion of mothballs to be a routine behavior, but instead considers this an episodic event. Accordingly, risk to children from episodic ingestion of para-dichlorobenzene was assessed.

Since no chemical-specific post-application data were submitted in support of para-dichlorobenzene, the Agency used exposure data from a naphthalene study, "Estimation of Homeowner Exposure to LX1298-01 (Naphthalene) Resulting from Simulated Residential Use as an Insect Repellent", for the short-term inhalation assessment. The Agency determined that this study provided the best currently available estimate of exposure levels to para-dichlorobenzene vapors for short-term durations, because it was based on the maximum label use rate for naphthalene, which matches that of para-dichlorobenzene. Therefore, the naphthalene homeowner exposure study was used as a surrogate for estimating para-dichlorobenzene levels for the short-term inhalation exposure scenario. In this study, concentrations were measured over a three day period near the treatment location (closets and drawers) and throughout the house. The average exposure levels corresponding to these locations were 0.85 and 0.66 mg/m³,

respectively. Due to the similar use and retreatment rates for mothballs containing naphthalene and para-dichlorobenzene, the Agency anticipates that the exposure levels of these chemicals when formulated as mothballs are similar. However, para-dichlorobenzene has a higher vapor pressure than naphthalene, and this indicates that the use of naphthalene data as a surrogate for para-dichlorobenzene does not necessarily result in a conservative risk estimate. To address this uncertainty, the Agency will require a confirmatory chamber study to determine levels of para-dichlorobenzene in the air resulting from use of mothballs at the maximum label rate.

For intermediate- and long-term post-application inhalation assessment, the Agency used studies conducted by EPA entitled “Total Exposure Assessment Methodology (TEAM)” to estimate exposure values. Among other things, these studies measured indoor residential concentrations of para-dichlorobenzene. The data indicate a seasonal dependence of the para-dichlorobenzene levels. The Agency used maximum mean concentration of 36.2 ug/m³ (winter value) to assess intermediate-term scenarios. For long-term assessment, an average of the seasonal value (21 ug/m³) was used.

Because no acute endpoint was selected, the Agency used the short-term incidental oral endpoint of 25 mg/kg/day derived from a 4-week dog oral toxicity study to estimate risk from episodic ingestion of one mothball. The Agency believes the risk estimate for mothball ingestion is conservative, since it is based on a comparison of episodic (one-time event) exposure duration to a toxic endpoint reflecting repeated short-term exposures. The residential risk assessment is also based on current label rates and use instructions, as well as on estimates of what and how much homeowners typically treat, from the Agency’s standard operating procedures for residential exposures and best professional judgment. For more information on the residential post-application assessment parameters, refer to the *Para-dichlorobenzene: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED)*, dated September 28, 2007.

The LOC for episodic ingestion is an MOE of 100. This includes the standard UF of 10X for intraspecies extrapolation and 10X for interspecies variation. For post-application inhalation exposure, the LOC is 30, based on a UF of 10X for intraspecies extrapolation and a UF of 3X for interspecies variations. While the post-application inhalation risk estimates are not of concern (MOEs are above 100), the episodic ingestion scenario is of concern, with an MOE below 1. The Agency performed additional calculations to determine the dose level required to result in a MOE of 100. Based on these calculations, oral consumption of anything greater than 0.25 mg/kg/day of para-dichlorobenzene results in a MOE less than 100 and is considered a risk of concern. This oral dose of para-dichlorobenzene, 0.25 mg/kg/day, is equivalent to a 15 kg toddler consuming 0.16% of one 2.35 g mothball. The residential post-application MOEs for para-dichlorobenzene are summarized in Table 3 below.

Table 3. Para dichlorobenzene Non-Cancer Residential Post-Application Risk		
Source of exposure	Exposed Population	MOE
Episodic mothball Ingestion		
Mothballs	Toddler	<1
Inhalation Short –Term		

Table 3. Para dichlorobenzene Non-Cancer Residential Post-Application Risk		
Source of exposure	Exposed Population	MOE
Mothballs	Adult (Accessing Treated Areas)	212
	Adult (Inhabiting Treated Home)	273
Inhalation Intermediate –Term		
Mothballs	Adult	1650
Inhalation Long- –Term		
Mothballs	Adult	160

6. Residential Cancer Risk

Generally, when the Agency determines that there is a plausible MOA for a carcinogen, a low dose linear extrapolation for cancer is not conducted. However, the Integrated Risk Information System (IRIS) program is currently reviewing the mode of action evidence for para-dichlorobenzene and has not yet made a determination of non-linearity. IRIS is a database of human health effects that may result from exposure to various substances found in the environment, and it is maintained by EPA’s National Center for Environmental Assessment (NCEA). IRIS was initially developed for EPA staff in response to a growing demand for consistent information on chemical substances for use in risk assessments, decision-making and regulatory activities. The information in IRIS is intended for those without extensive training in toxicology, but with some knowledge of health sciences. Since NCEA has not yet made a non-linearity determination, for the purposes of the present assessment, the Agency is presenting a linear low-dose extrapolation risk for cancer.

A draft IRIS document on para-dichlorobenzene was recently circulated for external peer review (Revised Final Draft, May 2006. EPA/635/R-03/015). In this document, NCEA concluded that a cancer risk assessment should be based on a low-dose linear extrapolation model, and the final draft of May 2006 provided two slope factors for hepatic tumors in male and female mice. The first was based on oral exposure (table 5-5, page 136), $1.7 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ and $4.0 \times 10^{-3} \text{ (mg/kg/day)}^{-1}$ for males and females, respectively. The second was based on inhalation exposure (pages 141 and 142), $4.5 \times 10^{-3} \text{ (mg/m}^3\text{)}^{-1}$ and $4.3 \times 10^{-3} \text{ (mg/m}^3\text{)}^{-1}$, for males and females, respectively. NCEA recommended an overall unit risk for both males and females of $4 \times 10^{-3} \text{ (mg/m}^3\text{)}^{-1}$ based on inhalation exposure. This unit risk should not be used with exposures exceeding the point of departure (23 mg/m^3), because above this level the fitted dose-response model better characterizes what is known about para-dichlorobenzene inhalation carcinogenicity. In addition to the slope factors, the draft IRIS document provided Bench Mark Concentration Doses at which a 10% response for liver tumors was seen in the mice (BMC_{10}) and its 95% lower bound (BMCL_{10}) based on inhalation exposures. The (BMC_{10}) and (BMCL_{10}) for hepatocellular adenoma or carcinoma in female mice were 41.3 mg/m^3 and 22.9 mg/m^3 , respectively.

Cancer risk estimates resulting from exposures to para-dichlorobenzene were calculated for homeowners handling mothballs and individuals living in homes treated with mothballs and inhaling mothball vapors. A Lifetime Average Daily Dose (LADD) was calculated and then

multiplied by a slope factor of $4 \times 10^{-3}(\text{mg}/\text{m}^3)^{-1}$, which was calculated by NCEA based on dose response data for hepatic tumors in male and female mice exposed to para-dichlorobenzene via inhalation. The estimates of cancer risk are based on the assumption of low dose linearity and range from 7.1×10^{-9} for dermal exposure during the application of mothballs to 6.0×10^{-5} for post-application inhalation exposure to mothballs.

For the estimation of cancer risk for dermal exposures of homeowners handling mothballs, dermal exposures were compared to inhalation endpoints. Cancer risks were assessed for dermal exposures using an inhalation endpoint, since systemic effects (liver tumors) were noted in the inhalation studies for para-dichlorobenzene. The slope factor is based on these systemic effects. If the toxic effects after inhalation exposures were localized (nose only) and not systemic, it would not be appropriate to include a cancer risk for dermal exposures that relied upon a toxic endpoint for localized effects resulting from inhalation exposures.

a. Residential Handler Cancer Risk

For the residential handler cancer risk estimate, a highly conservative assumption that adult individuals are exposed annually for 50 years out of a 70 year lifetime was used. In addition, the cancer risk estimates are conservative because the LADD calculated for dermal exposures do not include a dermal absorption factor; instead, 100% dermal absorption has been assumed.

Estimated cancer risks for dermal exposures of adults handling mothballs during application are below 1×10^{-6} using the linear approach and, therefore, are below the Agency's levels of concern. The cancer risks for dermal exposures of handlers are presented below in Table 4.

Application Method	Exposed Individual	Location	Dermal Average Daily Dose (mg/kg/day)	LADD (mg/kg/day)	Cancer Risk
Hand	Adult	Closet	0.0091	3.55×10^{-5}	4.9×10^{-8}
		Drawer	0.00134	5.20×10^{-6}	7.1×10^{-9}

b. Residential Post-Application Cancer Risk

Estimated para-dichlorobenzene cancer risks for post-application inhalation exposures are presented below in Table 5.

Exposed Individual	Inhalation Average Daily Dose (ug/m ³)	LADD (ug/m ³)	Cancer Risk
Adult	21	15	6.0×10^{-5}

Using linear low dose extrapolation and a slope factor of $4.0 \times 10^{-3} \text{ (mg/m}^3\text{)}^{-1}$, the cancer risk estimates could be as high as 6×10^{-5} . For the residential post-application cancer risk estimate, a highly conservative assumption that homeowners are exposed annually for 50 years out of a 70 year lifetime was used.

The linear low dose extrapolation model provides a range of cancer risks. As with all linear low dose extrapolation models, the range is bracketed by an upper bound and a lower bound on these risks. The 6×10^{-5} cancer risk estimate represents an upper bound on cancer risk for exposures to para-dichlorobenzene, but the cancer risk could be as low as zero. This is independent of the strengths and weaknesses of the cancer data. OPP believes that the carcinogenic risks are below the upper bound and may be closer to zero for para-dichlorobenzene for several reasons. In addition to the inherent uncertainty in the linear low dose extrapolation model estimates discussed above, as described in Section 2: Carcinogenicity of Para-dichlorobenzene, available evidence indicates that the mechanism leading to tumor formation in the livers of mice after exposure to para-dichlorobenzene is based on sustained mitogenic stimulation and proliferation of hepatocytes. This information forms the basis of a plausible mode of action for tumorigenesis in the mice livers. In addition, the BMCL_{10} (the lower limit of the benchmark concentration central estimate for a 10% response above background. Note: a 10% response is at the limit of sensitivity in most cancer bioassays) for hepatocellular adenoma or carcinoma formation in female mice is 22.9 mg/m^3 . If the BMCL_{10} is compared to the measured concentrations of para-dichlorobenzene in people's homes (0.021 mg/m^3), the BMCL_{10} is 1000 times higher than actual exposures. That is, there is a 1000-fold margin of safety between the concentration at which there is a 10% tumor response in test animals, at the lowest measurable incidence, and actual measured exposure in people's homes. Consequently, OPP believes the carcinogenic risk from this use is not of concern for the following reasons: 1) there is mechanistic data to support a lower cancer risk estimate based on a mitogenic mode of carcinogenic action, 2) conservatism in the exposure estimates, and 3) a large margin of safety between estimated human exposure and the point at which there is a measurable (10%) tumor response.

7. Aggregate Risk

Since para-dichlorobenzene does not have outdoor uses registered, which could result in drinking water exposure, or any food uses, which could result in dietary exposure, a dietary risk assessment was not conducted. Similarly, because dietary risk is not expected, an aggregate assessment combining residential, food, and drinking water exposure was not conducted. The Agency did not aggregate adult dermal exposures while handling para-dichlorobenzene products with inhalation post-application exposures, because there were no dermal effects noted at the highest dose tested (HDT). Inhalation and episodic (incidental) ingestion routes of exposure were not combined for toddlers in order to differentiate the occurrence of a discrete accidental event (assessed to give a worst-case estimate of risk) from the expected daily exposure via the inhalation route. It would not be appropriate to combine an accidental, episodic exposure for comparison to a short-(or longer) term endpoint.

8. Occupational Risk

The only occupational use of para-dichlorobenzene arises from use in empty beehives. Exposure from this activity is expected to be no higher than the handler (dermal) and post-application (inhalation) exposures from the indoor residential use of mothballs which were assessed. Risk estimates for residential handler and post-application exposures are protective of this occupational use and below levels of concern. As a result, a separate risk assessment for occupational exposures (handler and post-application) was not conducted for para-dichlorobenzene.

9. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), the California Pesticide Illness Surveillance Program, National Pesticide Information Center, and the National Institute for Occupational Safety and Health's (NIOSH) Sentinel Event Notification System for Occupational Risk (SENSOR) program.

The summary findings for the period 1993 to 2005 for para-dichlorobenzene, primarily from PCC data are:

- The proportion of symptomatic cases among those exposed in all population groups evaluated (occupation, non-occupational, children) were not significantly different from the overall, national composite average. Specifically, the proportion of symptoms among those followed and the proportion hospitalizations among those seen at a health care facility (HCF) is lower than the composite of all chemicals.
- Among children under the age of six, there were 3165 exposure cases to para-dichlorobenzene while the entire population has 4480; children represent the largest portion of the total exposed in the population (70.6%).
- There was an average of about 344 exposures per year, 33 symptomatic cases per year, and 38 cases per year seen in a health care facility across all population groups.
- An irregular decreasing annual trend is evident in the 12 year-span of data collected; the number of total exposed cases was reduced by half in this period.

B. Environmental Risk Assessment

Since there are no outdoor uses of para-dichlorobenzene, and indoor uses of para-dichlorobenzene are not expected to result in ecological exposure, an ecological risk assessment was not completed, as is described in the *Para-dichlorobenzene: EFED Memorandum in Support of the Reregistration Eligibility Decision*, dated May 8, 2007. This determination is confirmed in the *Para-dichlorobenzene: Addendum to EFED's Memorandum in Support of the Reregistration Eligibility Decision*, dated September 28, 2007, which states that para-dichlorobenzene is used for control of wax moths in empty beehives (EPA Reg. No. 61617-2), but is not an outdoor use. Label directions instruct users to apply at a maximum rate of 0.19 lbs a.i. for hives in storage. Users are instructed to air out hives before reuse, because residual para-dichlorobenzene would harm bees in a hive. In addition, para-dichlorobenzene must not be present in populated hives,

because the odor of para-dichlorobenzene could be absorbed by the honey, and para-dichlorobenzene has no food tolerances.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing para-dichlorobenzene as active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing para-dichlorobenzene.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing para-dichlorobenzene. The Agency has determined that para-dichlorobenzene-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Appendix A summarizes the uses of para-dichlorobenzene that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of para-dichlorobenzene, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of para-dichlorobenzene, the Agency has determined that products containing para-dichlorobenzene, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency will take regulatory action to address the risk concerns from the use of para-dichlorobenzene. If all changes outlined in this document are incorporated into the product labels, then all current risks for para-dichlorobenzene will be adequately mitigated for the purposes of this determination under FIFRA.

B. Public Comment Period

Because the risks associated with the use of para-dichlorobenzene were considered to be low, and the Agency intends to revisit the proposed mitigation measures during the review of naphthalene (a chemical with similar products and uses), the Agency determined an expedited one phase RED process was appropriate for para-dichlorobenzene, and a public comment period was not conducted. However, since the Agency is proposing mitigation measures for para-dichlorobenzene, a 60-day public comment period will be conducted after the RED is issued, and will be announced in the Federal Register. Comments may be submitted under Docket number EPA-HQ-OPP-2007-0937 at <http://www.regulations.gov>. The RED document and technical supporting documents for para-dichlorobenzene are also available to the public through EPA's electronic public docket and comment system, Regulations.gov, under docket identification (ID) number EPA-HQ-OPP-2007-0937. In addition, the para-dichlorobenzene RED document may be downloaded or viewed through the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that products containing para-dichlorobenzene are eligible for reregistration provided that specified label amendments are made. The following is a summary of the rationale for managing risks associated with the use of para-dichlorobenzene. Where labelling revisions are warranted, specific language is set forth in the summary table of Section V.

Residential Non-Cancer Risk

For non-cancer residential risk, the MOEs for all handler scenarios assessed were greater than 100 (i.e. were below the Agency's LOC), and therefore, no mitigation measures are required.

Residential post-application non-cancer risk (inhalation and episodic ingestion) was also assessed. The MOEs for all durations of post-application inhalation exposure were greater than 30, *i.e.*, the Agency's LOC, and therefore, no mitigation measures are required. The MOE for post-application episodic ingestion was less than 1, which is less than the target LOC of 100, and therefore, is of concern. The Agency believes the risk estimate for mothball ingestion is conservative and overestimates risk, since it is based on a comparison of episodic (one-time event) exposure duration to a toxic endpoint reflecting repeated short-term exposures. The Agency acknowledges there are uncertainties associated with both the toxicity data used for the episodic ingestion risk assessment and with the human incident report. However, the information available indicates a potential risk of concern. Because of the magnitude of the risk suggested by the MOE for episodic ingestion, the Agency has conducted risk mitigation discussions with the para-dichlorobenzene technical and end-use registrants, and recommends that mothballs no longer be marketed in such a way that individual moth balls are applied to areas accessible to children. To that end, the Agency intends to require that products be packaged in a way that would discourage children from eating the product. Sachets, for example, which are already used by some registrants for an end use moth repellent product, if made of a tear-resistant material, would make the moth ball product less accessible. In addition, the Agency will require precautionary label language which warns consumers of a possible episodic ingestion risk to children. The Agency will revisit these requirements in parallel with a review of naphthalene (a chemical with similar products and uses), currently scheduled for reregistration in 2008.

Residential Cancer Risk

Cancer risk estimates resulting from exposures to para-dichlorobenzene were calculated for homeowners handling mothballs (dermal), and individuals living in homes treated with mothballs and inhaling mothball vapors using a linear low dose extrapolation model.

Estimated cancer risks for dermal exposures of adults handling mothballs during application are below 1×10^{-6} using the linear approach and, therefore, are below the Agency's level of concern.

For the residential post-application inhalation risk estimate, OPP determined that carcinogenic risk is also not of concern. See Section III of this document for a discussion of residential post-application cancer risk.

Occupational Risk

The only occupational use of para-dichlorobenzene arises from use in empty beehives. Exposure from this activity is expected to be no higher than the handler (dermal) and post-application (inhalation) exposures from the indoor residential use of mothballs which were assessed. Risk estimates for residential handler and post-application exposures are protective of this occupational use and below levels of concern. As a result, a separate risk assessment for occupational exposures (handler and post-application) was not conducted for para-dichlorobenzene.

2. Endocrine Disruptor Effects

EPA is required under the FFDCFA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "*may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.*" Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, para-dichlorobenzene may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary.

The Agency has reviewed the registrations and other information for para-dichlorobenzene and concludes that this insecticide does not pose a risk of direct acute or chronic

effects to any species listed under the Endangered Species Act, since the registered uses for para-dichlorobenzene will not result in outdoor exposure to endangered species.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing para-dichlorobenzene. For the specific labeling statements, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that products containing para-dichlorobenzene are eligible for reregistration provided that the required label amendments are made. The Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data. Below are the label amendments that the Agency intends to require for para-dichlorobenzene to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of para-dichlorobenzene for currently registered uses has been reviewed and determined to be substantially complete. However, the Agency is requiring a confirmatory chamber study (875.2500) to determine levels of para-dichlorobenzene in the air resulting from use of mothballs at the maximum label rate. It is recommended that a study protocol be submitted to the Agency for review prior to the inception of the study.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 6.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Veronica Dutch at 703-308-8585.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 6. Generally, conditions for the distribution and sale of products bearing old

labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

For para-dichlorobenzene to be eligible for reregistration, all para-dichlorobenzene labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 6 describes how language on the labels should be amended.

Table 6. Summary of Labeling Changes for Para-dichlorobenzene		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	<p>“Only for formulation into an <i>insecticide/repellent</i> for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”</p> <p>“Special packaging for mothball, flake, and crystal end use products are required to reduce the risk that children will ingest the product.”</p>	Directions for use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards Statements	<p>“ENVIRONMENTAL HAZARDS”</p> <p>“Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.”</p>	Precautionary Statements: Environmental Hazards

Table 6. Summary of Labeling Changes for Para-dichlorobenzene		
Description	Amended Labeling Language	Placement on Label
End-Use Products Intended for Occupational Use		
PPE Requirements Established by the RED For All Formulations	<p>“Personal Protective Equipment (PPE)”</p> <p>“All applicators and other handlers must wear:</p> <ul style="list-style-type: none"> - Long sleeved shirt, - Long pants, - Shoes plus socks.” 	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	<p>“User Safety Recommendations”</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)
Episodic Ingestion Statements	<p>“IMPORTANT: This product can be harmful to children when ingested. Do not allow children to ingest the product.”</p>	Directions for Use

Table 6. Summary of Labeling Changes for Para-dichlorobenzene		
Description	Amended Labeling Language	Placement on Label
End-Use Products Intended for Residential Use		
Episodic Ingestion Statements	“IMPORTANT: This product can be harmful to children when ingested. Do not allow children to ingest the product.”	Directions for Use

Appendix A. Use Patterns Eligible for Reregistration for Para-dichlorobenzene					
Use Site	Formulation Type	Product Type	Maximum Application Rate/Applicationⁿ	Unit	Maximum Retreatment Interval
Beehives- Empty	Crystalline	N/S ¹	0.1875	lb/hive	NS
Birds	Crystalline	N/S	0.0313	lb/cage	NS
Household/Domestic Dwellings Contents	Crystalline	Balls, Flakes, Crystals, Cakes, and Sachets	0.02	lb/ft ³	7
Household/Domestic Dwellings Contents	Crystalline	Block	0.0249	lb/ft ³	7
Household/Domestic Dwellings Indoor Nonfood Handling Areas	Impregnated Material	Varpel Rope	9.86	ft/1000 ft ³	NS
Human Clothing	Crystalline	Balls, Flakes, Crystals, Cakes, and Sachets	0.02	lb/ft ³	7

1. Not specified.

2. Para-dichlorobenzene has neither reentry interval restrictions nor restrictions on the maximum number of application per year.

Appendix B

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 3058 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 3058 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B			
Data Supporting Guideline Requirements for the Reregistration of Para-dichlorobenzene			
REQUIREMENT		Use Pattern	CITATION(S)
PRODUCT CHEMISTRY			
New Guideline Number	Study Description		
830.1600	Description of Materials Used to Produce the Product	M	46460601
830.1620	Description of Production Process	M	46285301; 46460601
830.1670	Formation of Impurities	M	46285301; 46460601
830.1700	Preliminary Analysis	M	46285301
830.1800	Analytical Method	M	46285301
830.6302	Color	M	46285301
830.6303	Physical State	M	46285301
830.6304	Odor	M	46285301
830.6315	Flammability	M	46285301
830.6317	Storage Stability	M	46285301
830.6320	Corrosion Characteristics	M	46285301
830.7000	pH	M	46285301
830.7050	UV/Visible Absorption	M	Data Gap
830.7200	Melting Point	M	46285301
830.7220	Boiling Point/Boiling Range	M	46285301
830.7300	Density	M	46285301
830.7840	Water Solubility	M	46285301
830.7950	Vapor Pressure	M	46285301
TOXICOLOGY			
870.1100	Acute Oral Toxicity – Rat	M	40521001
870.1200	Acute Dermal Toxicity – Rabbit	M	40521001
870.1300	Acute Inhalation – Rat	M	41410901
870.2400	Acute Eye Irritation – Rabbit	M	42205301
870.2500	Acute Dermal Irritation - Rabbit	M	42205302
870.2600	Skin Sensitization – Guinea Pig	M	42205303
870.3150	90-Day Oral Toxicity- Dog	M	43988801
870.3200	21-Day Dermal Toxicity – Rat	M	41315001
870.3465	90-Day Inhalation Toxicity – Dog	M	41822801
870.3700	Prenatal Developmental Toxicity	M	42619601 (Rat); 40568001 (Rabbit)
870.3800	Reproduction and Fertility Effects – Rat	M	41108801

830.4100	Chronic Toxicity – Dog	M	43988802
870.4300	Combined Chronic Feeding/ Carcinogenicity	M	40521005 (Rat); 40521005 (Mouse)
870.5100	Bacterial Reverse Mutation	M	40521004; 40568002; 40568003
870.5275	Sex-linked Recessive Lethal Test in <i>Drosophila</i> <i>Melanogaster</i>	M	40521007
870.5300	Cytogenetics- Mouse Lymphoma Mutagenic Assay	M	40521007; 40521013; 40521014
870.5375	Cytogenetics – Sister Chromatid Exchange In CHO cells.	M	43368448; 43868210; 40521007
870.5395	In Vitro Mammalian Cytogenetics Tests	M	43368447; 40521012
870.5450	Rodent Dominant Lethal Assay	M	40521011
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture	M	40521008
870.5900	In Vitro Sister Chromatid Exchange Assay	M	40521007
870.6200	Acute Neurotoxicity Screening Battery	M	43350601
870.6200	Subchronic Neurotoxicity Screening Battery – Rat	M	43350602
870.7485	General Metabolism	M	41697801
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
875.2400	Dermal Exposure	M	43716501
870.2500	Inhalation Exposure	M	Data Gap

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard (South Building), 1777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The risk assessments and other supporting documents for para-dichlorobenzene are available in the Public Docket, under docket number EPA-HQ-OPP-2007-0937, and on the Agency's web page, <http://www.regulations.gov>. The docket contains risk assessments and related documents as of December, 2007.

Technical support documents for the Para-dichlorobenzene RED include the following:

Health Effects Documents

1. *Para-dichlorobenzene: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED)*, dated September 28, 2007.
2. *Para-dichlorobenzene: HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated September 27, 2007.
3. *Review of Paradichlorobenzene Incident Reports*, dated June 25, 2007.

Ecological Fate and Effects Documents

1. *Para-dichlorobenzene: EFED Memorandum in Support of the Reregistration Eligibility Decision*, dated May 8, 2007.
2. *Para-dichlorobenzene: Addendum to EFED's Memorandum in Support of the Reregistration Eligibility Decision*, dated September 28, 2007.

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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1671	Nadeau, H.G.; Oaks, D., Jr. (1961) Separation and analysis of chlorobenzenes in mixtures by gas chromatography. Analytical Chemistry 33(9):1157-1159. (Also~In~unpublished submission received Jan 26, 1969 under 9F0754; submitted by Olin Mathieson Chemical Corp., New York, N.Y.; CDL:091301-K)
4377	Childers, N.F. (19??) Bush berry culture: Chapter XXII. Pages 759- 780, 799-806, ~In~Modern Fruit Science. New Brunswick, N.J.: Rutgers Univ. (Also~In~unpublished submission received Nov 4, 1976 under 7E1882; submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:097579-A)
4899	Haberman, W.O.; Payne, J.R. (1962) Miscellaneous Insecticides: S.R. Project #25. (Unpublished study received Jun 19, 1962 under 602-104; submitted by Ralston Purina Co., St. Louis, Mo.; CDL: 231617-A)
4904	Uni-Research (1973) Evaluation of Dog Repellent Product: Technical Report. (Unpublished study received Dec 12, 1973 under 1663-11; submitted by Grant

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4909	Harmad Laboratories (1976) Use of Naphthalene as a General Insect-icide. (Unpublished study received Nov 16, 1976 under 1548-3; submitted by Vermex Co., Calabasas, Calif.; CDL:227450-C)
6007	Storer, T.I.; Jameson, E.W., Jr. (1965) Control of Field Rodents on California Farms. Davis: Univ. of California. (Agricultural Experiment Station, Extension Service circular 535; also~In~un- published submission received Apr 23, 1976 under 6704-78; sub- mitted by U.S. Dept. of Interior, Fish and Wildlife Service, Washington, D.C.; CDL:224030-I)
13189	Cooper, P.A. (1973) The Movement of Chloropicrin Vapor in Wood to Control Decay. Master's thesis, Oregon State Univ., Dept. of Forest Products. (Unpublished study received Apr 23, 1974 under 5316-17; submitted by Namco Chemicals, Inc., San Jose, Calif.; CDL:024054-C)
32762	Kissileff, A. (1941) Research Data. (Unpublished study received Aug 16, 1965 under 59-18; submitted by Burroughs Wellcome Co., Research Triangle Park, N.C.; CDL:000121-A)
32780	Miller, W.V. (1957) Kil-A-Mite: Further Improvements. (Unpublished study received Sep 22, 1969 under 59-105; submitted by Burroughs Wellcome Co., Research Triangle Park, N.J.; CDL:000127-A)
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34172	Nelson, C.R.; Watson, D.L. (1964) ?Efficacy of Dog Repellent Scram on Garbage Cans and Shrubs : Project No. 170-W64-1. (Unpub- lished study received Oct 8, 1964 under 239-2057; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:001451-A)
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34174	Davis, D.L.; Watson, D.L. (1964) Scram Bomb--Dog Repellency. (Un- published study including project no. 170-W64-1, received Dec 9, 1964 under 239-2057; submitted by Chevron Chemical Co., Rich- mond, Calif.; CDL:001453-A)

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44105	Hollingsworth, R.L.; Rowe, V.K.; Oyen, F.; et al. (1956) Toxicity of Paradichlorobenzene: Determinations on experimental animals and human subjects. American Medical Association Archives of Industrial Health 14(?/Aug):138-147. (Also~In~unpublished sub- mission received Oct 22, 1971 under 6718-7; submitted by Amway Corp., Ada, Mich.; CDL:103485-A)
51053	Grant Laboratories (1964) ?Data on Grant's Dog Repellent . (Com- pilation; unpublished study received Jun 5, 1964 under 1663-11; CDL:220938-A)
51533	Fulton, R.A. (1954) Letter sent to Fred Lodes dated May 17, 1954 ?Particle size determination on cans of Fuller Brush Co. Moth- proofer . (Unpublished study received on unknown date under 1574-9; submitted by Stanley Home Products, Inc., Westfield, Mass.; CDL:224117-A)
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53189	Alcor Products (1972) Data Relating to Safety of Repel Animal Repellent. (Unpublished study received Jun 24, 1974 under 20215- 1; CDL:051047-A)
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93918	Margard, W.L. (1978) In vitro Bioassay of Selected Compounds. (Unpublished study received Jan 25, 1982 under 748-161; prepared by Battelle Columbus Laboratories, submitted by PPG Industries, Inc., Barberton, Ohio; CDL:246648-D)
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	8550- 20; prepared by Rosner-Hixson Laboratories, submitted by Pro- Specialities, Inc., Wauwatosa, WI; CDL:240691-A)
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140757	Whitmire Research Laboratories, Inc. (1962) ?Efficacy: House Trainer . (Compilation; unpublished study received Dec 17, 1962; Dec 26, 1962; Feb 7, 1963 under 499-135; CDL:006067-A)
141838	Chacon Chemical Corp. (19??) [Product Chemistry and Toxicity Data for Paradichlorobenzene and Orthodichlorobenzene]. Unpublished compilation. 16 p.
152838	Valle-Herrera, V. (1984?) [Efficacy Data]: Repel #3 Rat and Mouse Repellent. Unpublished compilation prepared by Colegio de Inge- nios Quimicos de Jalisco, A. C. 5 p.
152839	Alcor Products Corp. (1985) Alcor's Rat and Mouse Repellent: Chem- istry: [Product Chemistry Data]. Unpublished compilation. 13 p.
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5001782	Johnson, H.R.; McIntire, M.S. (1975) Pesticide poisoning in children: a review from Children's Memorial Hospital, Omaha, Nebraska from 1960-1973_ Part I. Nebraska Medical Journal 60(2):40-43.
40465100	BSP Marketing, Inc. (1987) Submission of Data To Support the Regis- tration of Red Circle Pure Para Moth Balls: Product Chemistry Data. Transmittal of 1 study.
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40521000	Chlorobenzene Producers Assoc. (1988) Submission of Data in Respon- se to the Comprehensive Data Call-in Notice for Data on Para- dichlorobenzene. Transmittal of 14 studies.
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40521002	Hodge, M.; Palmer, S.; Bennett, I.; et al. (1977) Para-dichloro- benzene: Teratogenicity Study in Rats: Rept. No. CTL/P/340. Unpublished study prepared by Imperial Chemical Industries, Ltd. 58 p.
40521003	Giavini, E.; Broccia, M.; Prati, M.; et al. (1986) Teratologic Evaluation of p- dichlorobenzene in the rat. Bull. Environ. Contam. Toxicol. 37:164-168.

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40521005	National Toxicology Program (1987) Toxicology and Carcinogenesis Studies of 1,4-Dichlorobenzene in F344/N Rats and B6C3F1 Mice. NTP TR 319. US Dept. of Health and Human Services: US Govern- ment Printing Office. 198 p.
40521006	Conner, T.; Theiss, J.; Hanna, H.; et al. (1985) Genotoxicity of organic chemicals frequently found in the air of mobile homes. Toxicology Letters 25:33-40.
40521007	Chlorobenzene Producers Assoc. (1984) Summary Report: The Effect of Para-dichlorobenzene in a Battery of Genetic Toxicology Assays. Unpublished compilation prepared in cooperation with Bioassay Systems Corp. and Univ. of Wisconsin. 110 p.
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40521202	Kellerby, J. (1988) ?Inert Ingredient : Volume 2: Product Chemistry. Unpublished study prepared by Y-TEX Corp. in cooperation with Ciba-Geigy Corp. 52 p.
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40548601	Touhey, R. (1988) Paradichlorobenzene--Product Identity. Unpublished compilation prepared by Standard Chlorine Chemical Co. 18 p.
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